## Bio Medical Health Center<sub>Inc.</sub>

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Dockets Management Branch (HFA-305) Docket No. 98N-1265 Food and Drug Administration 5600 Fishers Lane Rockvile, MD 20857

20 May 1999

I object to the draft MOU being proposed by the FDA. In particular, I object to the definition of "inordinate amount," which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescreptions that can be shipped across state lines from specialized compounding pharmacies.

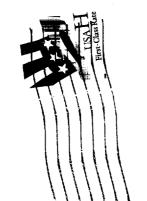
As a physician in practice in an area that borders on another state, and with a significant number of patients commuting from rural areas of another state for medical care in my urban area the services of a compounding pharmacy in the rural area are not available. Therefore, visiting patients commonly have their compounded medications prepared here and shipped across state lines to them in their home state. The current definitions as outlined in the MOU would result in patients not being able to obtain their necessary compounded medications if artificial and capricious limitations on the number of prescriptions the pharmacist may ship are imposed. The availability of compounded medications is a necessary part of modern practice and this type of restriction is both unnecessary and harmful to he public welfare. This MOU should be withdrawn.

Respectfully,

Corazon I. Ibarra, MD, HMD

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